

# Patients are Counting on Us: It's Time to Act

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**24<sup>th</sup> Global GS1 Healthcare Conference**  
October 2, 2013



THE WALL STREET JOURNAL

Tuesday, May 28, 2013

## Africa's Malaria Battle: Fake Drug Pipeline Undercuts Progress

- Customs in Angola discovered 1.4 million packets of counterfeit Coartem, used to treat malaria; Contained no active ingredient
- 1 in 10 Angolans is diagnosed with malaria every year
- If genuine, would be enough to treat half the malaria in Angola.
- A 2012 NIH study found that 35% of 2,300 malaria drugs tested were either fake or substandard.

Every incident like this undermines all of our efforts to help protect patient safety and save more lives.

# Tragic Consequences Not If... But When and Where



**Tainted cough syrup kills 21 in Panama**  
CDC investigation traces mysterious deaths to industrial

**The New York Times**

November 26, 2008

WORLD BRIEFING | AFRICA

**The New York Times**

February 21, 2012

**Substandard malaria drugs pose a threat to fight**

ard malaria  
g threat to  
the disease, a  
ed by the

federal government has  
concluded

Gutter oil is reproduced from meta

**CNN.com /US**

Updated 9:51 p.m. EST, Fri November 28, 2008

**FDA sets 'safe' levels for melamine in baby formula**

INTERNATIONAL  
**Herald Tribune**  
THE GLOBAL EDITION OF THE NEW YORK TIMES

**China recalls infant formula**

By Keith Bradsher

**CBS NEWS**

AP / February 7, 2013, 4:06 PM

**FDA warns about fake Avastin again**



**Pharmaceutical warehouse raid recovered**

04-May-2012

Enforcement officials in the USA have recovered all of the \$76m-worth of pharmaceutical products stolen in a raid on an Eli Lilly distribution centre in Enfield, Connecticut, in March 2010, making 11 arrests.



The notorious raid was notable not only for the value of the goods seized but also the sophistication of the attack, with the perpetrators disabling the security system and cutting the power to the building.

rx-360.org



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# By the Numbers...2012

- Large number of pharmaceutical crime incidents:  
**2,018**
- Medicines involved: **529**      Countries involved: **123**
- Percentage increase of life saving injectable medicines:  
**48%**



# By the Numbers...2012

- Total value of drugs impacted  
**\$321M**
- China and India (+81%) incidents  
**31%**
- Incidents hitting legitimate supply chain  
**483**
- Increase of legitimate supply chain incidents  
**13%**



# \$80M Burglary of Eli Lilly's Warehouse

## The Issues

- Perpetrators entered the facility by cutting a hole through the roof and disabling the electronic access control and alarm system
- Product removed through the shipping and receiving dock and loaded onto a tractor trailer(s)
- Multiple contributing factors

## The Results

- Perpetrators identified, arrested (5/12)
  - ✓ Identified by water bottle
  - ✓ All product recovered
- FDA Theft Reporting institutionalized
- Industry collaboration
  - ✓ Pharmaceutical Cargo Security



# Illicit Activity Impacts All Stages of the Supply Chain From:

- Raw materials
- Excipients
- APIs
- Components
- Drug products
- Packaging & Labeling
- Storage
- Distribution



# Illicit Activity is Present and Threatens the Safety of Medicines

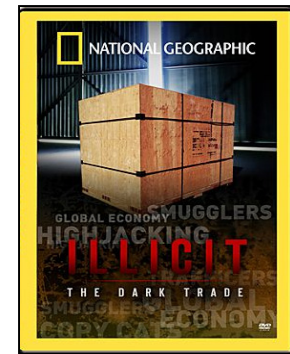
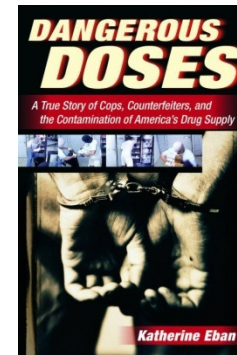
\$1000



The criminal element is present, active, and business savvy

Weak criminal penalties

Relatively safe for criminals





# Momentum is building

## Industry is...

- Conducting more audits which are more thorough
- Focusing on supply chain security
- Hearing the message leading to increased supplier transparency
- Implementing company specific solutions
- Improving and increasing the level of collaboration

**There is more to do because the threats are not slowing down. Rx-360 is a solution...**

# Serving patients is a privilege that comes with responsibilities

Our Mission:

Protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of materials within the supply chain

**Patient safety should never be used as a competitive advantage**

# Broad and Inclusive Membership

- Small and large Branded and generic companies
- Suppliers and manufacturers
- Companies are members not individuals
- 505(c)(6) nonprofit organization
- Worldwide Organization
- Volunteer based
- Designed to meet competition law requirements

# Rx-360 Membership Now Tops 80 Organizations!

## Manufacturers (25)

- AbbVie
- Amgen
- Amylin
- AstraZeneca
- Baxter
- Bayer
- Biogen Idec
- Boehringer Ingelheim
- Bristol-Myers Squibb
- Cephalon
- Eli Lilly
- Forest Labs
- GlaxoSmithKline
- Hospira
- Johnson & Johnson
- Merck & Co., Inc.
- Merz Aesthetics
- Mylan
- Novartis/Sandoz/Alcon
- Pfizer
- Roche/Genentech
- Sanofi-Aventis
- Takeda
- Teva
- Watson

## Suppliers (32)

- AMPAC Fine Chemicals
- Arch Pharmalabs
- Ash Stevens
- Ashland
- Avantor
- BASF
- Cambridge Major Labs
- Cardinal Health
- Doe & Ingalls
- DSM Nutritional Products
- Envirotainer
- Fagron
- GE Healthcare
- Hikal
- Hovione
- Labochim
- LifeConEx
- Life Technologies
- Ligand Pharmaceuticals
- Merck KGaA
- Multipharma
- Novozymes
- OSO BioPharmaceuticals
- Sartorius AG
- SICPA Holding
- Sigma Aldrich
- Spectrum Chemical & Laboratory Products
- TempTime
- VWR
- West
- York Container

## Auditors (11)

- Auckerman Consulting
- Blue Inspection Body
- PSC Biotech Corp.
- Regulatory Compliance Associates
- Rephine
- RMC Pharmaceutical Solutions Inc.
- Safis Solutions LLC
- SQA Services Inc.
- STS Consulting
- The Weaver Group

## Associations (15)

- APIC
- Council for Responsible Nutrition
- Anonymous Association
- Consumer Healthcare Products Ass (CHPA)
- European Fine Chemicals Group (EFCG)
- European Generic Medicines Ass (EGA)
- Anonymous Regulatory Body
- IPEC Americas
- IPEC Europe
- NSD Bio Group
- Parenteral Drug Association (PDA)
- PhRMA
- Pharmaceutical Supply Chain initiative (PSCI)
- Pharmaceutical Quality Group (PQG)
- ISPE

# This is Where Rx-360 is Currently Engaged

## Intelligence and External Affairs

- ✓ Monitoring & Reporting
- ✓ Flash Reports
- ✓ Alerts
- ✓ Supply Chain Threats
- ✓ Asia

## Supply Chain Security

- ✓ Incident Management
- ✓ Illegal Diversion
- ✓ Serialization
- ✓ Drug Shortages

## Audit Operations

- ✓ Joint Audits
- ✓ Shared Audits
- ✓ Auditor Qualification
- ✓ Licensing
- ✓ Finance
- ✓ Database

# Examples of Our Results

- Information packed web site
- Over 330 Flash Reports
- Over 100 Summaries of Legislation, Regulation or Guidance
- Several important standards for unmet needs
- 18 Alerts Issued
- Several White Papers documenting best practices
- Over 100 Audits
- Real time advice to manage crisis, i.e. Japan Tsunami

**www.Rx-360.org is your one stop location  
for securing the supply chain**

# Collaboration is a game changer...

## Rx-360 provides industry that opportunity

Protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of materials within the supply chain

1. Educating
2. Sharing information
3. Standardizing
4. Promoting best practices
5. Sharing Audits

www.Rx-360.org

### Rx-360.org Shares Information That Can Benefit Us All: **Acetonitrile Method**

Determination of Adulteration of Acetonitrile using Gas Chromatography with Thermal Conductivity Detection

PDA/FDA Regulatory Conf., Sept '09

www.Rx-360.org

### Since April 2009 Rx-360 Has Distributed Industry News to Registered Users

PDA/FDA Regulatory Conf., Sept '09

# Thank you

**For More Information**



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